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DEPARTMENT OF HEALTH & HUMAN SERVICES

US Food & Drug Administration
New York District
158-15 Liberty Ave.
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

April 21, 2006

William J. Reilly, Jr.
Owner
Elmira Seafood
456 W Washington Avenue
Elmira, New York 14901

Ref: NYK-2006-16

Dear Mr. Reilly:

We inspected your seafood processing facility, located at 456 W Washington Avenue, Elmira, New York 14901 on February 16 and 21, 2006. We found that you have serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123, and the Current Good Manufacturing Practice regulation for foods, Title 21, Code of Federal Regulations, Part 110 (21 CFR 123 & 110). In accordance with 21 CFR 123.6(g), failure of a processor of fish or fishery products to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of Part 123, renders the fish or fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your refrigerated pasteurized crabmeat in hermetically sealed cans is adulterated, in that it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation and the Fish and Fisheries Products Hazards & Controls Guidance through links in FDA's home page at www.fda.gov.

Your significant violation was as follows:

You must have a HACCP plan that, at a minimum, lists monitoring procedures and their frequency for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for refrigerated pasteurized crabmeat in hermetically sealed cans, lists monitoring procedures at the receiving and storage critical control points that are not adequate to control *Clostridium botulinum* growth and toxin formation. Your HACCP plan states that at receiving you will take the flesh temperature of the incoming product and ensure that ice completely surrounds the product. At the storage critical control point you

list that you will monitor ice and cooler temperature [REDACTED]. At the beginning of our inspection, your refrigerated pasteurized crabmeat in hermetically sealed cans was not observed to be stored on ice. In addition, the manager of your firm stated that your refrigerated pasteurized crabmeat in hermetically sealed cans is not received on ice, or with other cooling media. As a result, we would not expect that you would list monitoring procedures associated with the presence of ice at either your receiving or your storage critical control points.

- With regard to receiving, FDA does not object to monitoring product temperatures for those products transported less than 4 hours using a calibrated thermometer. However, for products in transit for extended time periods (e.g. longer than 4 hours), FDA suggests the use of a method of continuous temperature monitoring such as a time/temperature data logger, recorder thermometer, or a high temperature alarm with 24 hour monitoring capabilities that monitors the ambient air temperature of the truck cargo area. Your monitoring frequency should be continuous by the instrument itself, with a visual check of the transit record at each delivery.
- With respect to refrigerated storage, the FDA recommends use of a continuous monitoring device capable of continuously monitoring the temperature of the cooler using a continuous recording thermometer or a high temperature alarm with 24 hours monitoring capabilities. Your monitoring frequency should be continuous by the instrument itself with a visual check of the instrument and the temperatures at least once per day.

In addition, the Food and Drug Administration has determined that your facility is subject to the registration requirement in Section 415 of the Act (21 U.S.C. § 350d) and our implementing regulation at 21 CFR Part 1, Subpart H. The failure to register a facility as required is a prohibited act under Section 301(dd) of the Act (21 U.S.C. § 331(dd)). Our records indicate that, to date, your facility has not been registered with FDA.

The owner, operator, or agent in charge of your facility, or an individual authorized by your facility's owner, operator, or agent in charge, should register the facility with FDA immediately. Registration may be accomplished on-line at <http://www.access.fda.gov>. We strongly encourage the use of electronic registration because it will result in an automatic confirmation of registration and automatic issuance of a registration number.

Alternatively, the owner, operator, or agent in charge of this facility, or an individual authorized by the facility's owner, operator, or agent in charge, may register the facility by mail or fax (e.g., if you do not have reasonable access to the Internet) using FDA's food facility registration form, Form 3537. This form may be obtained by calling the FDA Industry Systems Help Desk at 1-800-216-7331 or 301-575-0156, or by writing to the agency at the following address:

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U.S. Food and Drug Administration, HFS-681
5600 Fishers Lane
Rockville, MD 20857

When completed, the form may be faxed to (301) 210-0247 or mailed to the address above. FDA will process registrations submitted by mail or fax and provide a facility's registration number using the same method used to submit the registration to FDA.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating in violation of Section 402(a)(4) of the Act (21 U.S.C. § 342(a)(4)) and the seafood HACCP regulation. We may also take further action to enjoin your firm from operating in violation of Section 415 of the Act (21 U.S.C. § 350d) and 21 CFR Part 1, Subpart H.

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You should include in your response documentation such as HACCP and verification records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

This letter may not list all the violations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulation (21 CFR Part 123) and the Current Good Manufacturing Practice regulation (21 CFR Part 110), and is registered in accordance with the Food Facility Registration regulation (21 CFR Part 1, Subpart H). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Anna Alexander, Compliance Branch, US Food and Drug Administration, New York District, 158-15 Liberty Avenue, Jamaica, New York 11433. If you have questions regarding any issues in this letter, please contact Anna Alexander at 718-662-5683.

Sincerely,

A handwritten signature in dark ink, appearing to read "Steven B. Simpson", is written over a horizontal line.

Steven B. Simpson
Acting District Director